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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,669	11/01/2001	Robert H. Broyles	OKL010-107/00727A	5327

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EXAMINER

LI, QIAN J

ART UNIT	PAPER NUMBER
1632	10

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/003,669

Applicant(s)

BROYLES ET AL.

Examiner

Q. Janice Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:

- I. Claims 1-3, 11-13, and 19-22 are drawn to a method for suppressing a disease caused or enhanced by effects of intracellular iron mismanagement using ferritin-H protein. Classified in class 514, subclass 2.
- II. Claims 1, 4, 11, 14, 19, 21 are drawn to a method for suppressing a disease caused or enhanced by effects of intracellular iron mismanagement by inducing expression of an endogenous ferritin gene. Classification is to be determined depending on the agents used for inducing the expression.
- III. Claims 1, 5, 6, 11, 15, 16, 19, 21 are drawn to a method for suppressing a disease caused or enhanced by effects of intracellular iron mismanagement by repressing the expression of the ferritin-L or derivatives using an antisense DNA in vivo. Classified in class 514, subclass 44.
- IV. Claims 1, 7, 8, 10, 11, 17-19, 20, 21, 23 are drawn to a method for suppressing a disease caused or enhanced by effects of intracellular iron mismanagement by introducing a nucleic acid vector encoding a ferritin-H protein in vivo. Classified in class 514, subclass 44.
- V. Claims 1, 7, 9-11, 17-19, 21 are drawn to a method for suppressing a disease caused or enhanced by effects of intracellular iron mismanagement by first

introducing a nucleic acid vector encoding ferritin-H protein ex vivo to a cell.

Classified in class 424, subclass 93.21.

2. The inventions are distinct, each from the other because of the following reasons.

Inventions II-V and I are independent and distinct inventions. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different methods use materially different substances, i.e. proteins, anti-sense DNAs, vectors encoding a ferritin protein, genetically modified cells, and other agents. The different substances have distinct pharmacokinetics, biodistribution, and mode of operation upon administration to the patient, accordingly different method require different method steps, have different modes of operation, and require distinct technical considerations.

Each group of invention further comprises multiple inventions. The claims embrace treating distinct diseases, for example, a sickle cell disease, and neurological diseases, such as Parkinson's disease, Huntington's disease, Friedreich's ataxia and related neuromuscular disorders. The listed diseases are distinct in cells involved, genes involved, and unique pathogenesis. Thus, different methods require distinct considerations even though intracellular iron mismanagement may be one of the symptoms in the named diseases. For example, for sickle cell anemia, the target cell would be hematopoietic cells, particularly the red blood cells; whereas the neurological disorders involve neuronal cells. Consequently, the targeting ligand, means of delivery

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of the therapeutic substance would require different considerations and search criteria,

Applicants are required to elect a distinct disease for examination in this application.

Please note, these are distinct inventions, not a species election.

Invention group II may contain distinct inventions, further restriction may be necessary if group II is elected, and upon clarification of agents for inducing endogenous ferritin-H gene expression.

The differences of the Inventions I-V are further underscored by their divergent classification and independent search criteria.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search criteria, it would impose an undue burden to the Office if all the groups are examined together, thus, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention: Invention I, IV, and V are directed to a method using a ligand or antibody capable of binding to a specific receptor on the surface of a cell. If one of the inventions IV, V, and I is elected, further election of a species, drawn to a particular receptor of a particular cell type, is necessary.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3, 7-13, and 17-23 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
January 24, 2003

ANNE M. WEHBE PH.D
PRIMARY EXAMINER

